DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021337/S-030

**SUPPLEMENT APPROVAL**

Merck & Co., Inc.
Attention: Robert A. Fromtling, Ph.D.
Director, Regulatory Affairs
P.O. Box 2000, RY 33-212
Rahway, NJ 07065-0900

Dear Dr. Fromtling:

Please refer to your supplemental new drug application submitted and received May 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (ertapenem).

We acknowledge receipt of your submissions dated July 23 and December 7, 2009.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Post-Marketing Experience subsection of the label to include altered mental status (including aggression, delirium), dyskinesia, myoclonus, and tremor.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, submitted on December 7, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-337/S-030**."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Susmita Samanta, M.D., Regulatory Project Manager, at 301-796-0803.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-21337 | SUPPL-30 | MERCK AND CO INC | INVANZ (ERTAPENEM SODIUM) |

---

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

---

/s/

SUMATHI NAMBIAR
12/13/2009